UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE BIOGEN IDEC, INC.	:	Civil Action
SECURITIES LITIGATION	:	No. 05-10400-WGY
		LEAVE TO FILE GRANTED 7/31/07

REPLY MEMORANDUM OF LAW
IN FURTHER SUPPORT OF DEFENDANTS' MOTION
TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES **PAGE(S)**

STATUTES **PAGE(S)**

PRELIMINARY STATEMENT[1]

Plaintiffs stake their entire case upon non-particularized allegations that Defendants' statements concerning TYSABRI® safety and marketability potential were knowingly false when made because Defendants "knew" at some unspecified point "during the clinical trials" that TYSABRI® (i) caused PML and (ii) also caused other "opportunistic" infections, some of which resulted in patient deaths.[2] Entirely absent from the 435-paragraph Amended Complaint, however, is even one specific allegation of fact to support such erroneous charges. Indeed, there are no particularized allegations stating (i) when any Defendant knew of PML or any other "opportunistic" infection but nevertheless made purportedly false or misleading statements, (ii) what specific negative safety data was known or should have been known to have been potentially caused by TYSABRI® but hidden from the FDA or the clinical investigators or (iii) why the observance of infections other than PML are significant -- either clinically or for the purposes of the securities laws. Devoid of such allegations, the Amended Complaint cannot meet the strict pleading requirements of the PSLRA and Rule 9(b).

In addition to that independently dispositive failure, the Amended Complaint fails to raise any inference of scienter, let alone the requisite strong one. The Opposition does not -- and cannot -- rebut Defendants' arguments that Plaintiffs' allegations of stock sales fail to establish the requisite strong and highly likely inference of scienter because a substantial majority of those sales were made pursuant to Rule 10b5-1 trading plans. Tellingly, the

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[1] Capitalized terms herein shall have the same meaning as in the Revised Memorandum Of Law In Support Of Defendants' Motion To Dismiss The Consolidated Class Action Complaint (Docket No. 86) (cited as "Initial Brief at __"), filed November 20, 2006. In addition, "App. Ex. __" refers to the Appendix Of Public Records (Docket No. 84), filed November 15, 2006.

[2] Plaintiffs' Memorandum Of Law In Opposition To Defendants' Revised [sic] Motion To Dismiss The Consolidated Class Action Complaint at 12-13 (Docket No. 92) (the "Opposition") (cited as "Opp. at __").

Opposition argues that the Court should ignore the public record fact of those trading plans because Plaintiffs chose to omit them from the Amended Complaint. That, of course, is not the law in this (or any other) Circuit.

The Opposition also fails to overcome the protective applicability of the safe harbor provisions of the PSLRA to all of Defendants' forward-looking statements, and confirms that the Amended Complaint fails to state any actionable control person or insider trading claims.

In sum, the Opposition does nothing to salvage the Amended Complaint's pleading inadequacies. The grand conspiracy that Plaintiffs offer to the Court -- that dozens of scientists, physicians and executives "must have known" that TYSABRI® was likely to kill -- is as baseless as it is offensive. This is exactly the sort of case that does not deserve to get out of the starting gate.

REPLY POINTS

I. THE OPPOSITION CONFIRMS THAT PLAINTIFFS HAVE NOT -- AND CANNOT -- PLEAD SECURITIES FRAUD WITH PARTICULARITY

A. Plaintiffs' Non-Specific Allegations Of Safety Data Allegedly Observed During The TYSABRI® Clinical Trials Are Insufficient To Support A Claim Of Securities Fraud

The Amended Complaint alleges that 89 of Defendants' public statements during the putative class period (February 18, 2004 through February 28, 2005) were false or misleading at the time that each was made because Defendants allegedly knew that TYSABRI® was unsafe and never going to be a widely marketable drug. (Am. Compl. ¶¶ 97, 129.) The Opposition *argues* that this theory is supported by its conclusory allegations that sometime prior to the onset of the putative class period Defendants "knew" that TYSABRI® (i) caused PML and (ii) caused other "opportunistic infections in patients taking Tysabri during the Class Period" and certain patients died from "these [other] infections during [TYSABRI®'s] clinical trials." (Opp. at 12.)

As Biogen Idec's Dr. Panzara presented during the FDA Advisory Committee hearings in March 2006 (more than a year after the end of the putative class period), only 8 patients taking TYSABRI® (out of approximately 3,900, or 0.2%) developed any so-called "opportunistic" infections. (Initial Brief at 21.) Three of those patients developed PML, and the remaining five patients developed other "opportunistic" infections. (FDA Trans. at 62-63, App. Ex. 15.) As demonstrated below (and in the Initial Brief), Plaintiffs' allegations regarding knowledge of PML and other "opportunistic" infections do not satisfy the rigorous pleading requirements of the PSLRA and Rule 9(b) and, accordingly, fail as a matter of law to state a claim of securities fraud. Indeed, when those allegations are scrutinized, Plaintiffs' case is exposed as nothing more than impermissible fraud-by-hindsight.

1. The Opposition Fails To Address -- Let Alone Rebut -- Defendants' Arguments Concerning Plaintiffs' Allegations Of PML

The Opposition *argues* that the Amended Complaint "clearly provides particularized facts demonstrating that prior to and during the Class Period, Defendants knew (or recklessly disregarded) that Tysabri caused PML." (Opp. at 12.) Tellingly, Plaintiffs do not cite a single Amended Complaint paragraph -- let alone the requisite "all facts" mandated by the PSLRA (15 U.S.C. § 78u-4(b)(1)) -- to support that baseless argument.

In the Initial Brief, Defendants demonstrated the insufficiency of Plaintiffs' allegations concerning (i) when Defendants became aware that two patients developed PML (Am. Compl. ¶¶ 318-22) and (ii) the misdiagnosis of the one patient in the Crohn's trial who had actually died of PML (id. ¶¶ 156-58). (Initial Brief at 25-26 and 18, respectively.) As to the first set of allegations, the Opposition fails to address that argument at all, implicitly conceding that those allegations are insufficient as a matter of law.

As for the allegations concerning the patient in the Crohn's trials, Plaintiffs assert that two "confidential sources" believe that the misdiagnosis was either "an effort by Defendants to conceal the true diagnosis or malpractice," and that those conclusory assertions are sufficient to raise an issue of fact. (Opp. at 23.) Not so. Plaintiffs cannot avoid the particularity requirements of the PSLRA and Rule 9(b) by pointing to two unsupported conclusory allegations and labeling them issues of fact. Indeed, those purported "confidential sources" provide nothing in the way of particularity and do not even purport to have personal knowledge of that patient or any interactions with any Defendant. (Initial Brief at 18.) Those sort of non-specific allegations from purported "confidential sources" are insufficient. In re Vertex Pharm., Inc. Sec. Litig., 357 F. Supp. 2d 343, 354 (D. Mass. 2005) (rejecting allegations of confidential sources who did not have "personal knowledge" of the facts attributed to them).

2. Plaintiffs' Allegations Of Other "Opportunistic" Infections And Purported Deaths Are Insufficient To Demonstrate Fraud

Similarly unavailing are Plaintiffs' arguments concerning the observance of other "opportunistic" infections in the remaining 5 patients, and certain alleged deaths from such infections "during [TYSABRI®'s] clinical trials." (Opp. at 12-15.) Those allegations fail to support a claim of securities fraud for at least two independently sufficient reasons:

First, TYSABRI® was suspended (and reintroduced with a boxed warning label) because of the observance of PML, not any other "opportunistic" infection(s). There are no allegations at all (whether particularized or conclusory) that explain why any of those "opportunistic" infections (in the absence of PML) rendered any of Defendants' statements concerning TYSABRI®'s safety or marketability potential knowingly false or misleading when made. Indeed, with full knowledge of those other "opportunistic" infections, the FDA nevertheless granted accelerated approval for TYSABRI®.

Second, Plaintiffs fail to allege with particularity when those purported "opportunistic" infections were observed and, crucially for purposes of their fraud claims, when any of those infections (or any deaths from those infections) were diagnosed as potentially related to TYSABRI®. Rather than plead those requisite facts with particularity, Plaintiffs instead *argue* that those infections occurred "during the drug's clinical trials." (Opp. at 12 (emphasis omitted).) But that is insufficient because TYSABRI® clinical trials were ongoing during the entire putative class period. Absent particularized facts as to when those other "opportunistic" infections occurred and what assessments were made as to the causality of any negative safety data, Plaintiffs have simply not adequately alleged all facts with the requisite specificity regarding what Defendants knew, when they knew it or how they knew it was attributable to TYSABRI®.

a. Plaintiffs fail to allege *why* "opportunistic" infections other than PML support a claim of fraud

Plaintiffs *argue* that the observance of "opportunistic" infections other than PML undermined Defendants' statements concerning the safety and marketability of TYSABRI® but fail to *allege* any particularized facts to support that conclusion. (Opp. at 7.) Nor could they. TYSABRI® dosing was voluntarily suspended because of the observance of PML in two patients in the MS clinical trials, not because of any other "opportunistic" infection. (2/28/05 Press Release, App. Ex. 6.) Further, upon the FDA-approved market reintroduction of TYSABRI®, a boxed warning was added to the product labeling warning of the risk of PML, not "opportunistic" infections. (Am. Compl. ¶ 362; TYSABRI® Package Insert at 1, App. Ex. 16.) TYSABRI®'s revised label states:

- "Because of the risk of PML, TYSABRI® is available only through a special restricted distribution program called the TOUCH™ Prescribing Program." (TYSABRI® Package Insert at 1, App. Ex. 16) (emphasis added); and

- "Because TYSABRI® increases the risk of [PML] . . . TYSABRI® is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, alternate multiple sclerosis therapies." (Id. (emphasis added).)

Further rebutting Plaintiffs' argument is the public record fact that on November 23, 2004, notwithstanding any "opportunistic" infections then observed, the FDA nevertheless granted accelerated approval for TYSABRI® as a treatment for relapsing forms of MS. (11/23/04 Press Release, App. Ex. 4.) Indeed, in granting accelerated approval, the FDA commented that TYSABRI® "has an acceptable safety profile . . . for the treatment of patients with relapsing forms of MS" and "compelling evidence of efficacy." (Medical Review at 101, App. Ex. 12 (emphasis added).)

Plaintiffs attempt to avoid this dispositive acknowledgment by recklessly asserting without any Rule 11 basis whatsoever that Defendants failed to disclose serious adverse events to the FDA. (Am. Compl. ¶ 129.) In the Initial Brief, Defendants demonstrated in detail how the very documents incorporated into the Amended Complaint conclusively rebut those allegations. (Initial Brief at 18-26.) The Opposition (understandably) fails to address those arguments in any meaningful way, except to erroneously assert that "Defendants admit in their Memorandum [that] none of the FDA materials, including the medical review . . . included any mention of opportunistic infections." (Opp. at 21 (emphasis added).) To the contrary, Defendants demonstrated that the Medical Review in fact discusses the death resulting from pulmonary aspergillosis (Initial Brief at 21-22) -- an "opportunistic" infection and the very case that Plaintiffs purport to rely upon now (Opp. at 13).

In short, there are no particularized factual allegations demonstrating why (in the absence of PML) that any of those 5 other "opportunistic" infections made any of Defendants' statements concerning TYSABRI®'s safety or marketability potential knowingly (or recklessly) false or misleading when made.

b. Plaintiffs' further failure to plead *when* any "opportunistic" infections were observed and *when* those infections were diagnosed as potentially related to TYSABRI® is dispositive

Equally dispositive of Plaintiffs' allegations is the Amended Complaint's lack of particularized facts as to when those 5 other "opportunistic" infections occurred and when, if at all, they were diagnosed as potentially related to (or caused by) TYSABRI®.

The Opposition attempts to side-step the requirement of *alleging* when purported "opportunistic" infections occurred by merely *arguing* that Defendants were "aware" of infections and deaths that "occurred in the Tysabri clinical trials" by no later than February 18, 2004, because some of those trials were completed by that time. (Opp. at 13.) But that argument is insufficient because at least six TYSABRI® clinical trials were still occurring during the entire putative class period. (Medical Review at 55, App. Ex. 12.) Indeed, the two PML cases that resulted in the voluntary suspension of TYSABRI® marketing occurred in patients who were then participating in MS clinical trials (2/28/05 Press Release, App. Ex. 6). The Opposition repeats no less than 12 times that "opportunistic" infections occurred "during the Tysabri clinical trials" (Opp. at 1, 5, 7, 12-14), but fails to acknowledge the public record fact that those clinical

trials were still ongoing even on the final day of the putative class period. That itself is grounds for dismissal.[3]

The Amended Complaint also does not allege when those "opportunistic" infections (or any alleged deaths from those infections) were diagnosed as potentially related to TYSABRI®. For example, the Amended Complaint alleges that "***seventeen deaths***" occurred during the clinical trials, "***thirteen of which were in patients taking Tysabri***" (Am. Compl. ¶ 133 (emphasis in original)), but, without more, this *non sequitur* fails to allege the cause of death or whether those deaths were diagnosed as potentially related to TYSABRI®. (See Initial Brief at 20-21.) Indeed, in commenting on those known deaths, the FDA stated that they "do not represent a clear safety signal, given the presence of confounding factors . . . and the lack of a substantial difference in mortality rates between [TYSABRI®] and placebo-treated subjects (0.2% vs. 0.2%)." (Ross Memo at 8, App. Ex. 13 (emphasis added).)

Indeed, absent particularized allegations of when those "opportunistic" infections were observed, and when any negative safety data was determined to be potentially related to TYSABRI® infusions -- and there are none -- there can be no claim of fraud. Carney v. Cambridge Tech. Partners, Inc., 135 F. Supp. 2d 235, 257 (D. Mass. 2001) (court restricted to the "immediate context of each statement" in deciding a case alleging securities fraud).

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[3] Plaintiffs' mistaken assertions as to when the clinical trials concluded is further highlighted in footnote 8 of the Opposition. (Opp. at 13.) Plaintiffs attempt to criticize Defendants for purportedly comparing allegations of "opportunistic" infections that "occurred ***during*** the clinical trials (¶ 134)" to those that the Opposition claims "occurred ***after*** the trials [¶ 153]." (Id. at 13 n.8 (emphasis in original).) However, and in addition to the numerous inadequacies with the allegations in ¶ 153 of the Amended Complaint (see Initial Brief at 17), the clinical trials were still ongoing after TYSABRI® was approved in November 2004 and, accordingly, it is impossible to discern what the allegations in ¶ 153 of the Amended Complaint even refer to (further demonstrating the lack of particularity with those allegations).

B. Plaintiffs' "Red-Flag" Allegations Are Insufficiently Particular To Support A Claim Of Securities Fraud

Plaintiffs also argue that Defendants ignored (or recklessly disregarded) "countless . . . red flag warnings" that they claim demonstrate that TYSABRI® "turns off" the immune system. (Opp. at 15; Am. Compl. ¶ 97.) But none of those alleged "red flags" are described with the particularity required by the PSLRA. Further, and wholly unaddressed in the Opposition, the publicly disclosed results from the TYSABRI® clinical trials conclusively rebut Plaintiffs' unfounded assertions. (See Initial Brief at 16-18.)

The Opposition's reliance on purported animal studies conducted by Biogen Idec and Elan are insufficient to support a claim of fraud. (Opp. at 16-17.) Plaintiffs argue that some animals experienced "unexplained deaths," and conclude that Defendants were "reckless in not following up" those studies. (Id.) As an initial matter, Plaintiffs' allegations in this regard are so vague and conclusory that they are utterly meaningless. (Am. Compl. ¶¶ 101, 103; Initial Brief at 13-15.) Further, the FDA analyzed all animal studies and concluded that TYSABRI® is "generally well tolerated in the animal models studied." (Medical Review at 17, App. Ex. 12.) Yet again, those allegations are nothing more than impermissible fraud-by-hindsight.

Plaintiffs' arguments of hypothetical academic discussions are equally non-specific and unavailing. (Opp. at 15-16.) First, none of those theoretical discussions mention the risk of PML. That alone is sufficient to defeat those allegations. Second, as demonstrated in the Initial Brief, the Amended Complaint fails to allege any of the necessary particulars such as which Defendant (if any) Dr. Miller purportedly raised his alleged concerns with, when this discussion occurred and what was said. (Initial Brief at 16.) The allegations concerning Dr.

Steinman are similarly non-particular; Plaintiffs fail to allege what was said at any conference or which Defendant (if any) participated.[4] (Id.)

C. Plaintiffs' Argument That The "Confidential Sources" Are Adequately Described Does Not Cure The Lack Of Particularized Allegations From Those Alleged Sources

The Opposition essentially argues that so long as Plaintiffs adequately allege an undisclosed source's position and duties, that any statement from them (no matter how conclusory or non-specific) is sufficient to survive a motion to dismiss in this Circuit. (Opp. at 17-18.) Not so. Even if the "confidential sources" are sufficiently described, that does not end the inquiry because it is the allegations from those sources that must nevertheless be particularized to support a claim of fraud. See In re Cabletron Sys., Inc., 311 F.3d 11, 30 (1st Cir. 2002) (holding that allegations attributed to anonymous sources were sufficient at the pleading stage so long as they contained "specific descriptions of the precise means through which [the alleged fraud] occurred") (emphasis added).

In this case, none of the "confidential sources" provide the critical particulars of when any infections were observed, when those infections were diagnosed as potentially related to TYSABRI®, why any specific alleged negative safety data rendered any of Defendants'

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[4] The Opposition also grossly mischaracterizes Dr. Steinman's publicly available 2004 article. (Opp. at 16.) Dr. Steinman simply did not conclude that TYSABRI® "turns off" the immune system as Plaintiffs allege. (Initial Brief at 14.) Rather, Dr. Steinman stated that while TYSABRI® was specific, it was not, in his view, specific enough. (Article dated July 9, 2004, at 213-14, App. Ex. 11 (stating that TYSABRI® had not "shown the level of exquisite specificity originally envisioned") (emphasis added).) Simply put, Plaintiffs attempt to create a "red flag" where none exists. Indeed, Plaintiffs understandably fail to explain why the FDA failed to act on this (or any other) purported "red flag."

statements false or misleading, or what any Defendant "knew" concerning TYSABRI® safety or marketability potential and when they knew it.[5] (Initial Brief at 22-24.)

For example, the Opposition relies on a "Data Entry Clerk" for the allegation that "***sixty to seventy adverse events were reported daily***" during the MS trials. (Opp. at 23 (emphasis in original).) From that allegation, Plaintiffs assert "[t]he sheer volume of adverse events and Defendants absolute failure to report any material level of adverse events is highly probative of Defendants' scienter." (Id. at 23.) The allegation from the Data Entry Clerk concerning the absolute number of adverse events is meaningless without, at a minimum, a particularized allegation concerning what percentage of those adverse events were reported from patients taking TYSABRI® versus patients taking placebo. The patients participating in the clinical trials are very sick -- they have MS. Adverse events in MS patients are expected frequently and, indeed, the FDA stated that the "incidence of severe adverse events was generally low in this study, for an MS population." (Medical Review at 64, App. Ex. 12 (emphasis added).) Further, during all of the clinical trials, "adverse events and serious adverse events were balanced between [TYSABRI® and placebo] groups." (FDA Trans. at 66:8-9, App. Ex. 15).) Simply put, the Data Entry Clerk's allegations are probative of nothing.

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[5] The Opposition claims that "with respect to each source, Plaintiffs have pled the source's position, the dates the source was employed in that position and the duties of that position." (Opp. at 17 (emphasis added).) This is demonstrably wrong. The Amended Complaint does not plead any of those allegations with respect to at least half of the inexplicably anonymous group, i.e., confidential sources 3, 4, 7 and 8. See, e.g., Am. Compl. ¶ 144 ("a neurologist formerly affiliated with the Yale University School of Medicine who was directly involved in the Tysabri clinical trials for MS ('CS 3') confirmed . . . ." Conspicuously absent from this allegation are necessary descriptions such as what this source's purported role in the clinical trials was and when he/she participated in any such trials. (See also Am. Compl. ¶¶ 117 and 156.)

II. THE OPPOSITION DOES NOT OVERCOME PLAINTIFFS' FAILURE TO PLEAD A *STRONG* INFERENCE OF SCIENTER

The Opposition argues that the Amended Complaint raises a strong inference of scienter because of the allegations concerning (i) "opportunistic" infections, (ii) Defendants' alleged failure to report adverse events to the FDA, (iii) the "confidential sources" and (iv) motive and opportunity. (Opp. at 20-27.) Because the lack of particularity of the allegations concerning (i)-(iii) are discussed above, Defendants address below only insufficiencies of the motive and opportunity allegations (id. at 23-27).[6]

A. Plaintiffs' Allegations Of Insider Stock Sales Fail To Raise A *Strong* Inference Of Scienter

The Opposition does not even attempt to defend Plaintiffs' failure to plead that a substantial majority of the stock sales they claim raise a strong inference of scienter were executed pursuant to Rule 10b5-1 trading plans. Instead, Plaintiffs ask the Court to ignore that public record fact because that was not "referenced in the Complaint . . . and, thus, cannot be considered by the Court at this juncture." (Opp. at 25.) But at the motion to dismiss stage, "[w]hat matters . . . is whether plaintiffs have placed [the defendant's] trading in context by addressing in their complaint whether [he] sold his stock pursuant to a Rule 10b5-1 trading plan

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[6] Unable to plead knowledge with the requisite particularity, Plaintiffs argue that Defendants are presumed to know alleged facts because they claim TYSABRI® was "Biogen's primary source of future growth." (Opp. at 15 n.12.) Plaintiffs' blanket assertion is as erroneous as it is contrary to the long-established principle in this Circuit (and others) that a strong inference of scienter cannot be imputed on the basis of an individual's position. See, e.g., Maldonado v. Dominguez, 137 F.3d 1, 9-10 (1st Cir. 1998) (rejecting allegations that defendants must have known facts by virtue of their executive positions). Moreover, courts in other jurisdictions have flatly rejected the "core business" doctrine at the heart of Plaintiffs' assertion of implied knowledge. See, e.g., In re Read Rite Corp. Sec. Litig., 335 F.3d 843, 848-49 (9th Cir. 2003) (imputing scienter on basis that "facts critical to a business's core operations or an important transaction generally are . . . apparent . . . to the company and its key officers" would violate the PSLRA) (citation omitted).

formulated before the alleged fraudulent scheme and why, if he did, this does not undercut a strong inference of scienter." Fener v. Belo Corp., 425 F. Supp. 2d 788, 814 (N.D. Tex. 2006) (granting motion to dismiss) (emphasis added).

In this case, Plaintiffs have not put any of Defendants' alleged trading in context because they completely omitted those trading plans, a fact readily available in the Form 4s filed with the SEC.[7] (See App. Exs. 17-20.) In any event, courts frequently find -- at the motion to dismiss stage -- that sales made pursuant to a Rule 10b5-1 trading plan are "not suspicious." Wietschner v. Monterey Pasta Co., 294 F. Supp. 2d 1102, 1117 (N.D. Cal. 2003) (granting motion to dismiss); In re Netflix, Inc. Sec. Litig., Civ. A. No. 04-2978-FMS, 2005 WL 1562858, at *8 (N.D. Cal. June 28, 2005) (granting motion to dismiss in part because sales were pursuant to a Rule 10b5-1 trading plan).

In short, the Opposition maintains that the Court should blind itself to the public record fact of the Rule 10b5-1 trading plans. That proposition is (i) absurd, (ii) telling in that Plaintiffs tacitly admit that they need the Court to ignore facts in order to argue scienter and (iii) inconsistent with case law expressly authorizing consideration of public records at the motion to dismiss stage. In re Ibis Tech. Sec. Litig., 422 F. Supp. 2d 294, 300 (D. Mass. 2006) (holding

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[7] In the First Circuit, a strong inference of scienter is not plead when "viewed in light of the complaint as a whole, there are legitimate explanations for the behavior that are equally convincing." In re Credit Suisse First Boston Corp., 431 F.3d 36, 49 (1st Cir. 2005) (emphasis added). Indeed, not only must the inference of scienter be strong, it also must be "highly likely." Ezra Charitable Trust v. Tyco Int'l, Ltd., 466 F.3d 1, 6 (1st Cir. 2006). In short, Rule 12(b)(6) "does not require the court to turn a blind eye to the universe of possible conclusions stemming from a given fact or set of facts. . . . In this instance, the plaintiffs' suggested inference simply does not achieve the level of strong probability needed to satisfy the PSLRA's pleading requirements." Credit Suisse, 431 F.3d at 51 (emphasis added).

that in ruling on a motion to dismiss the court may consider, among other things, "official public records") (quotation omitted).[8]

B. Plaintiffs' Allegations Of A Desire To Earn Bonuses Fail To Raise A *Strong* Inference Of Scienter

The Opposition cites to several cases outside this Circuit for the proposition that potential bonus compensation raises a strong inference of scienter. (Opp. at 26-27.) Plaintiffs, however, fail to address the cases in the Initial Brief from this Circuit holding that such allegations are insufficient as a matter of law. Ezra Charitable Trust v. Tyco Int'l, Ltd., No. 02-MDL-1353-PB, Civ. 03-CV-1355-PB, 2005 WL 2127619, at *4 (D.N.H. Sept. 2, 2005) (dismissing complaint and holding allegations that defendants sought to make misstatement in order to receive substantial salaries and bonuses insufficient to raise strong inference of scienter), aff'd, 466 F.3d 1 (1st Cir. 2006); In re Eaton Vance Corp. Sec. Litig., 206 F. Supp. 2d 142, 154 (D. Mass. 2002) (dismissing complaint and holding that plaintiffs' allegations of motive based on general financial incentives insufficient to raise a strong inference of scienter).

Further, there are no allegations at all concerning such necessary details about how the bonuses were calculated, whether they were discretionary, how they were approved, how individual executives were selected to receive bonuses, what benchmarks were considered in evaluating the award of bonuses, and when those performance benchmarks were established.

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[8] The Opposition's argument concerning Mr. Rohn's trading in connection with his retirement is equally unavailing. (Opp. at 26 n.26.) Plaintiffs claim that Mr. Rohn's trade on February 18, 2004, which occurred before he announced his retirement, was "suspicious." First, when Mr. Rohn announced his retirement misses the point -- as a matter of law stock trading by an executive preparing to retire is not unusual or suspicious. Greebel v. FTP Software, Inc., 194 F.3d 185, 206 (1st Cir. 1999). Second, Mr. Rohn's February 18, 2004, trade was made pursuant to a 10b5-1 trading plan. (App. Ex. 20.) That fact alone negates Plaintiffs' strong inference argument.

III. THE OPPOSITION FAILS TO OVERCOME THE SAFE HARBOR PROVISIONS OF THE PSLRA

The Opposition argues that forward-looking statements are protected by the PSLRA's safe harbor provisions only if "they are properly identified as such, accompanied by meaningful cautionary language and are made without actual knowledge of their falsity." (Opp. at 27 (emphasis added).) First, the actual knowledge safe harbor is independent; forward-looking statements made without actual knowledge of their falsity are protected even if they are not identified as forward-looking. In re Ibis, 422 F. Supp. 2d at 310 (holding that forward-looking statements made without actual knowledge of their falsity are protected "even if the forward-looking statement is not accompanied by meaningful cautionary statements"). Indeed, in order to overcome this safe harbor, Plaintiffs must plead with particularity actual knowledge of falsity, recklessness is insufficient. Id. at 310-11.

Second, Plaintiffs mistakenly contend that a forward-looking statement accompanied by meaningful cautionary language is not protected by the statutory safe harbor upon a proper pleading of actual knowledge of falsity. (Opp. at 27.) Plaintiffs' argument is rebutted by the very case they purport to rely, which provides that forward-looking statements accompanied by meaningful cautionary language "escape[] liability" even if those statements were "knowingly false and willfully fraudulent." In re Stone & Webster, Inc. Sec. Litig., 414 F.3d 187, 212 (1st Cir. 2005). See also In re Ibis, 422 F. Supp. 2d at 310 ("if a statement is accompanied by 'meaningful cautionary language,' the defendants' state of mind is irrelevant").

Third, Plaintiffs' argument that the statements identified in the Initial Brief are not forward-looking is nonsensical, and ignores the plain language of those statements. (Opp. at 27-28.) See, e.g., Am. Compl. ¶ 178 ("total revenues are targeted to grow 15%"); id. ¶ 203 ("[w]e believe the potential MS market . . . will grow to $6 billion" (emphasis omitted)).

IV. THE OPPOSITION CONFIRMS THAT THE CONTROL PERSON AND INSIDER TRADING ALLEGATIONS FAIL TO STATE A CLAIM

As an initial matter, Plaintiffs do not -- and cannot -- argue that their failure to state a primary violation of the Exchange Act requires dismissal of their control person and insider trading claims. (Opp. at 29-30.) Plaintiffs instead argue that to the extent they have adequately plead a Section 10(b) violation, then they have stated claims against all Defendants for control person liability and/or insider trading. (Id.)

A. The Control Person Claim Should Be Dismissed Because Plaintiffs Fail To Plead Culpable Participation As To *Any* Defendant

Plaintiffs do not dispute that they have not adequately plead culpable participation. (Id.) Rather, Plaintiffs argue that "culpable participation is not an element of a Section 20(a) claim in the First Circuit." (Id. at 30 n.32.) Although the First Circuit has expressly declined to rule whether the pleading of culpable participation is required to state a Section 20(a) control person claim -- leaving it to the district courts to decide in the first instance -- such a requirement is consistent with the PSLRA's heightened pleading requirements, and this Court should follow the numerous other courts in other jurisdictions that have already adopted that standard.[9]

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[9] See, e.g., SEC v. First Jersey Sec., Inc., 101 F.3d 1450, 1472 (2d Cir. 1996) (holding that in order to establish a *prima facie* case for control person liability under Section 20(a), plaintiffs must show, among other things, "that the controlling person was in some meaningful sense a 'culpable participant' in the primary violation") (citation omitted) (emphasis added), cert. denied, 522 U.S. 812 (1997); In re Yukos Oil Co. Sec. Litig., No. 04 Civ. 5243 (WHP), 2006 WL 3026024, at *23-24 (S.D.N.Y. October 25, 2006) (dismissing Section 20(a) claim against an individual defendant where plaintiffs "alleged no particularized facts of [defendant's] culpable participation in Yukos' allegedly fraudulent misstatements and omissions").

B. The Insider Trading Claim Should Be Dismissed *At Least* As To Messrs. Kellogg And Bucknum

Even if Plaintiffs have stated a primary Exchange Act violation -- and they have not -- the insider trading claim should nevertheless be dismissed against Messrs. Kellogg and Bucknum. Although the Amended Complaint purports to assert an insider trading claim against Mr. Kellogg (Am. Compl. ¶¶ 40, 426-35), the Opposition concedes that Plaintiffs do not allege that Mr. Kellogg traded Biogen Idec securities during the putative Class Period (Opp. at 25 n.23). Accordingly, the Section 20A claim fails as a matter of law against Mr. Kellogg.

Further, a primary violation against each insider must be alleged in order to state a Section 20(A) insider trading claim against any such insiders. See In re Qwest Commc'ns Int'l, Inc., 396 F. Supp. 2d 1178, 1200 (D. Colo. 2004) (holding that "plaintiffs' §20A claim must be dismissed as to [certain defendants] because the plaintiffs have not stated a §10(b) claim as to these defendants"). None of the cases Plaintiffs cite stand for the contrary position. (Opp. at 29 n.31.) Because Plaintiffs concede that they do not state a primary violation against Mr. Bucknum (Am. Compl. ¶ 38), the Section 20A against him must be dismissed.

V. NO FURTHER AMENDMENT SHOULD BE PERMITTED

Plaintiffs ask this Court for leave to file yet another amended complaint, but nowhere explain how they can correct the deficiencies in the current Amended Complaint. (Opp. at 30 n.33.) Plaintiffs' request to engage in an iterative process of filing complaint after complaint should be rejected. Plaintiffs, and the several law firms working for them, had more than eighteen months between the filing of this case and the filing of the Amended Complaint to investigate their claims of securities fraud, but are only able to "plead their case with determined imagination, but little factual substance." Carney, 135 F. Supp. 2d at 257 (denying request for leave to amend complaint made in a "footnote in [plaintiffs'] memorandum in opposition to

[defendants'] motion to dismiss."). It is not Defendants' (or the Court's) role to effectively comment on draft complaints *seriatim* to assist Plaintiffs in meeting their pleading burden. Plaintiffs have had more than a "fair shot" and still cannot state a claim. The Amended Complaint should be dismissed once and for all right now, with prejudice.

CONCLUSION

For all the foregoing reasons, as well as those stated in Defendants' Initial Brief (Docket No. 86), Defendants' motion to dismiss should be granted in its entirety, and the Amended Complaint should be dismissed with prejudice and without leave to further amend.

Dated: July 31, 2007
Boston, Massachusetts

Respectfully submitted,

/s/ James R. Carroll

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CERTIFICATE OF SERVICE

I, Michael S. Hines, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on July 31, 2007.

Dated: July 31, 2007

/s/ Michael S. Hines
Michael S. Hines